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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,135	07/13/2004	Fabio Giannessi	2818-207	7877
23117 7590 06/14/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER YOUNG, SHAWQUIA	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 06/14/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/501,135	GIANNESI ET AL.	
	Examiner	Art Unit	
	Shawquia Young	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date  
:7/13/04, 1/29/07, 1/30/07, 5/17/07.

## **DETAILED ACTION**

Claims 1-9 are currently pending in the instant application.

### **I. *Priority***

The instant application is a 371 of PCT/IT03/00007, filed on January 13, 2003 and claims benefit of Foreign Application ITALY RM2002A000016, filed on January 15, 2002.

### **II. *Information Disclosure Statement***

The information disclosure statement (IDS) submitted on May 17, 2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

The information disclosure statements (IDS) submitted on January 30, 2007, January 29, 2007 and July 13, 2004 are in partial compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been partially considered by the examiner.

### **III. *Restriction/Election***

#### **A. *Election: Applicant's Response***

Applicants' election with traverse of Group I in the reply filed on May 3, 2007 is acknowledged. The traversal is on the ground(s) that: the methods of use may be rejoined once the product claims are found to be allowable.

All of the Applicants' arguments have been considered but have been found

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persuasive.

Applicants request that the method claims may be rejoined once the product claims are found to be allowable. As mentioned in the Restriction Requirement on pages 6-8, the method claims will be rejoined once the product claims are allowable.

Subject matter not encompassed by elected Group I are withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected inventions.

#### IV. Rejections

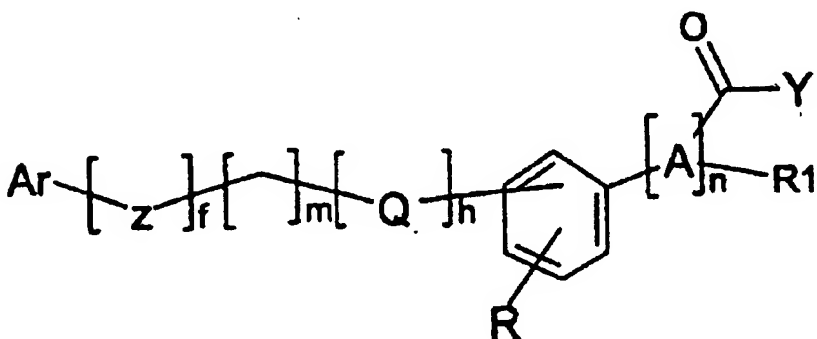
##### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3,6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by *Sahoo, et al.* (US 5,368,966) and Kawamatsu, et al. The instant elected invention claims a compound with the formula



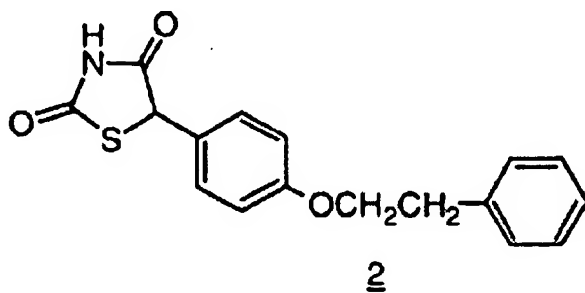
wherein A is CH; Ar is

phenyl, possibly substituted by halogens, NO<sub>2</sub>, OH, C<sub>1-4</sub> alkyl and alkoxy, said alkyl and

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alkoxy possibly substituted by at least one halogen; **m** is from 0 to 3; **n** is the number from 0 or 1; **Q** is O; **Z** is as defined in claim 1; **f** is 0; **R** is selected from **R**<sub>2</sub>, **OR**<sub>2</sub>; **R**<sub>1</sub> is as defined in claim 1; **R**<sub>2</sub> is selected from H, straight or branched C<sub>1</sub>-C<sub>4</sub> alkyl, possibly substituted by at least one halogen; **R**<sub>3</sub> is as defined in claim 1; **W** is selected from OH, **OR**<sub>4</sub>, NH<sub>2</sub>; **R**<sub>4</sub> is straight or branched C<sub>1</sub>-C<sub>4</sub> alkyl; **Y** is selected from OH, **OR**<sub>5</sub>; NH<sub>2</sub>; **R**<sub>5</sub> is as defined in claim 1. Claim 6 is drawn to compounds of the elected invention as medicines. Claim 7 is drawn to pharmaceutical compositions containing at least one compound of the elected invention in mixtures with pharmaceutically acceptable vehicles and/or excipients.

The *Sahoo, et al.* reference teaches phenylthiazolidinedione aldose reductase



inhibitors such as

(See page 5,

compound 2) and the activity of this compound in a diabetic mouse model. This species of compound anticipates the genus compound of the instant invention, wherein the genus structure and its definitions are stated above.

The *Kawamatsu, et al.* reference teaches thiazolidinedione derivatives for the treatment of diabetes, hyperlipidemia, etc. Some examples of these derivatives are such as compounds 1, 2, 12, etc. in example 9 (See column 8, example 9). The references also teaches pharmaceutical compositions of these compounds. This species of compound anticipates the genus compound of the instant invention, wherein

the genus structure and its definitions are stated above.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, variable A can be defined as CX, where as X appears to be unknown. However, the variable X is not defined anywhere in the claim. Therefore, the claims are indefinite because it is unclear what X encompasses. In claims 1 and 3, the term "possibly" is not defined by the claim, the specification does not provide a definition on what the term "possibly" encompasses. The interpretation of the Examiner is that it is substituted, however another interpretation could be that it is not substituted.

**V. Objections**

***Claim Objection-Non Elected Subject Matter***

Claims 1-7 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should submit an amendment deleting the non-elected subject matter.

*Claim Objections*

Claim 13, 16 and 18 are objected to because of the following informalities: In Claim 1, "or" is missing after the last two groups in variable A; n should be a zero not the letter O in the variable n; "and" is missing between the two groups in variable R; "and" is missing between the last two groups in variables R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, W and Y. In claim 5, "and" is missing between the last two compounds. In claim 7, there is an exclamation point after the term "and". Appropriate correction is required.

***Specification***

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because the abstract contains the term "said". The abstract also has the term "medinies" misspelled. There is no period at the end of the abstract. Correction is required. See MPEP § 608.01(b).



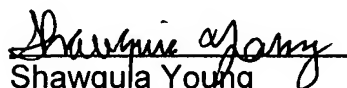
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## VI. Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 6:00 AM-2:30PM.

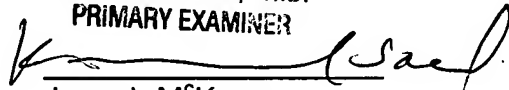
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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